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LAHIVE & COCKFIELD, LLP FLOOR 30, SUITE 3000 ONE POST OFFICE SQUARE BOSTON, MA 02109			EXAMINER	
			WESTERBERG, NISSA M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/852,966	Applicant(s) KADDURAH-DAOUK, RIMA
	Examiner Nissa M. Westerberg	Art Unit 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

1) Responsive to communication(s) filed on 09 April 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 68 - 70, 84, 85, 88, 92 - 94 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 68 - 70, 84, 85, 88, 92 - 94 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08c)
 Paper No(s)/Mail Date _____ 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Applicants' arguments, filed April 9, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 68 – 70, 84, 85, 88 and 92 – 94 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 5, 9 and 25 – 29 of U.S. Patent No. 6,242,491 further in view of Ozlen (US 5,441,740). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008 and those set forth below.

3. Claims 68 – 70, 84, 85, 88 and 92 – 94 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 5 and 7 – 10 of U.S. Patent No. 7,186,754 further in view of Ozlen (US 5,441,740). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008 and those set forth below.

4. Claims 68 – 70, 84, 85 and 92 – 94 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 –

6, 12 and 13 of copending Application No. 11/649145 further in view of Ozlen (US 5,441,740). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008 and those set forth below.

Applicants indicate that upon indication of allowable subject matter, the filing of terminal disclaimers will be considered. As such an indication has not been made and no terminal disclaimers filed, these rejections are maintained for the reasons of record set forth in the Office Action mailed October 9, 2008.

Response to Arguments

5. Applicant's arguments with respect to claims 68 – 70, 84, 85 and 92 – 94 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 68 – 70, 84, 85 and 92 – 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5,702,688) in view of Ozlen (US 5,441,740), Fujimura (US 5,939,078) and Pischel (US 5,863,939).

Yu discloses the treatment of cosmetic and dermatological conditions such as wrinkles (abstract). The compositions used in these methods can include creatine (col 34, ln 3 – 7). These compositions can be administered topically (col 1, ln 16 – 19). The compositions can also include sunscreen agents (col 12, ln 63).

Yu et al. does not disclose the administration of a composition comprising creatine ascorbate, a skin preserving agent such as EDTA or zinc oxide or titanium dioxide as the sunscreen agent.

Ozlen discloses a topical composition comprising alpha hydroxy acids, salicylic acid, bromelian, papain and disodium EDTA (col 3, ln 50 – col 4, ln 18) for treating skin conditions such as dry skin and wrinkles (col 1, ln 47 – 51).

Fujimura et al. discloses a wrinkle care product (abstract). The product comprises compound 8 (creatine; col 8) or an acid addition salt (col 3, ln 22). Fujimura

et al. also discloses that inorganic powders for UV protection (sunscreens) such as zinc oxide or titanium oxide can be present in the wrinkle care product (col 6, ln 49 – 51).

Pischel et al discloses that while creatine has many useful properties (col 1, 37 – 50), creatine salts often decompose into creatinine, but that creatine ascorbates do not decompose over time to form this product and therefore have a long shelf life (col 2, ln 10 – 12).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate creatine ascorbate, zinc oxide or titanium dioxide as the sunscreen agent and a skin preserving agent such as EDTA into the creatine containing composition taught by Yu et al. and to administer this composition to a subject, such as a human. The person of ordinary skill in the art would have been motivated to use creatine ascorbate as Pischel et al. discloses that the ascorbate salt form is more stable over time than other creatine salts. The inclusion of zinc oxide or titanium oxide would have been obvious as Yu et al. teaches that sunscreen agents can be included in the wrinkle treating composition and Fujimura teaches that zinc oxide or titanium oxide are suitable sunscreen agents for use in creatine containing wrinkle care products. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**. The inclusion of a skin preserving agent such as EDTA in the composition is obvious as the combination of two compositions taught

for the same purpose in the art, namely cosmetic compositions for the treatment of wrinkles, one containing creatine and sunscreen agent taught by Yu et al. and the other containing EDTA as taught by Ozlen, results in the combination of creatine active ingredient with EDTA.

As put forth in the Board decision mailed July 2, 2008, the failure of Yu et al. to appreciate the benefit provided by creatine is immaterial (p 5, last paragraph). As the active step of the method in the instant claims and the cited prior art are the same (administration of a topical composition comprising creatine ascorbate, EDTA and zinc oxide or titanium dioxide), the requirements of the method in the preamble of the claim (e.g., increasing energy reserves in the skin or sustaining energy production in the skin) is necessarily met.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/

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Supervisory Patent Examiner, Art Unit 1618

NMW